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PTO/SB/21 (09-04)

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<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	10/823,426	
	Filing Date	April 12, 2004	
	First Named Inventor	Naweed MUHAMMAD	
	Art Unit	1618	
	Examiner Name	M. Young	
Total Number of Pages in This Submission	8 + 22 refs.	Attorney Docket Number	524522001300

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	MORRISON & FOERSTER LLP (Customer No. 25226)		
Signature			
Printed name	Lisa A. Amii		
Date	September 11, 2006	Reg. No.	48,199

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Aurbill No. EV 456263259 US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Signature: *Rosemarie Puljo-Salneron*  
(Rosemarie Puljo-Salneron)

Patent

Docket No. 524522001300



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of:  
Naweed MUHAMMAD et al.

Examiner: M. Young

Group Art Unit: 1618

Serial No.: 10/823,426

Filing Date: April 12, 2004

For: METHODS AND COMPOSITIONS FOR  
ADMINISTRATION OF TRPV1  
AGONISTS

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

Applicants would like to draw the Examiner's attention to the co-pending applications listed below:

Application Serial No. 11/354,349, filed February 14, 2006, by Muhammad et al. and

Application Serial No. 11/396,161, filed March 30, 2006, by Bley

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;  
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **524522001300**.

Dated: September 11, 2006

Respectfully submitted,

By   
Lisa A. Amii

Registration No.: 48,199  
MORRISON & FOERSTER LLP  
755 Page Mill Road  
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(650) 813-5674



Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	2	Complete if Known	Application Number	10/823,426
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Filing Date	April 12, 2004
First Named Inventor	Naweed MUHAMMAD
Art Unit	1618
Examiner Name	M. Young
Attorney Docket Number	524522001300

## U.S. PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/M.Y./	1	US-2001/0002406-A1	05-31-2001	Robbins	
/M.Y./	2	US-2004/0202707-A1	10-14-2004	Muller	
/M.Y./	3	US-RE 37,934-E	12-10-2002	Hoffmann	
/M.Y./	4	US-4,927,667	05-22-1990	Nuwayer	
/M.Y./	5	US-4,952,402	08-28-1990	Sparks et al.	
/M.Y./	6	US-5,028,535	07-02-1991	Buechler et al.	
/M.Y./	7	US-5,665,378-A	09-09-1997	Davis et al.	
/M.Y./	8	US-5,869,533-A	02-09-1999	Holt	

## FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
/M.Y./	9	EP-1 568 365-A1	08-31-2005	Hisamitsu Pharmaceutical Co. Inc.		
/M.Y./	10	WO-98/53825-A1	12-03-1998	Algos Pharmaceutical Corporation		
/M.Y./	11	WO-2004/089361-A1	10-21-2004	LTS Lohmann Therapie- Systeme AG		

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M.Y./	12	Bennett, G.J. (October 15, 1998). "Neuropathic Pain: New Insights, New Interventions," <i>Hosp. Pract.</i> 33(10):95-98.	
/M.Y./	13	Bley, K.R. (2004). "Recent Developments in Transient Receptor Potential Vanilloid Receptor 1 Antagonist-Based Therapies," <i>Expert Opin. Invest. Drugs</i> 13(11):1445-1456.	
/M.Y./	14	Daniels, R. (August 2004). "Strategies for Skin Penetration Enhancement," <i>Skin Care Forum</i> , Issue 37, located at <a href="http://www.scf-online.com/english/37_e/37_e_pr/skinpenetration37_e_pr.html">http://www.scf-online.com/english/37_e/37_e_pr/skinpenetration37_e_pr.html</a> , last visited July 28, 2006, 11 pages.	
/M.Y./	15	Drugs.com. (2006). Drug Information for Capasacin (Topical) located at <a href="http://www.drugs.com/cons/Zostrix.html">http://www.drugs.com/cons/Zostrix.html</a> , last visited July 27, 2006, five pages.	
/M.Y./	16	Dworkin, R.H. (November-December 2002). "An Overview of Neuropathic Pain: Syndromes, Symptoms, Signs, and Several Mechanisms," <i>Clin. J. Pain</i> 18(6):343-349.	
/M.Y./	17	Frerick, H. et al. (November 2003). "Topical Treatment of Chronic Low Back Pain with a Capsicum Plaster," <i>Pain</i> 106(1-2):59-64.	
/M.Y./	18	Galer, B.S. et al. (September-October 2002). "The Lidocaine Patch 5% Effectively Treats all Neuropathic Pain Qualities: Results of a Randomized, Double-Blind, Vehicle-Controlled, 3-Week Efficacy Study With Use of the Neuropathic Pain Scale," <i>Clin. J. Pain</i> 18(5):297-301.	

Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
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pa-1086504

Substitute for form 1449/PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/823,426		
		Filing Date	April 12, 2004		
		First Named Inventor	Naweed MUHAMMAD		
		Art Unit	1618		
		Examiner Name	M.Young		
Sheet	2	of	2	Attorney Docket Number	524522001300

/M.Y./	19.	Harden, N. et al. (May 2003). "Unmet Needs in the Management of Neuropathic Pain," <i>J. Pain Symptom Management</i> 25(5S):S12-S17.	
/M.Y./	20.	Hautkappe, M. et al. (June 1998). "Review of the Effectiveness of Capsaicin for Painful Cutaneous Disorders and Neural Dysfunction," <i>Clin. J. Pain</i> 14(2):97-106.	
/M.Y./	21.	International Search Report for PCT Application No. PCT/US2006/012271 filed on March 30, 2006, mailed on July 25, 2006, five pages.	
/M.Y./	22.	Keitel, W. et al. (2001). "Capsicum Pain Plaster in Chronic Non-Specific Low Back Pain," <i>Arzneimittelforschung</i> 51(II):896-903.	
/M.Y./	23.	Levin, J. et al. (March 21, 2005). "The Correlation Between Transepidermal Water Loss and Percutaneous Absorption: An Overview," <i>J. Controlled Release</i> 103(2):291-299.	
/M.Y./	24.	Rice, A.S. et al. (November 2001). "Gabapentin in Postherpetic Neuralgia: A Randomised, Double Blind, Placebo Controlled Study," <i>Pain</i> 94(2):215-224.	
/M.Y./	25.	Robbins, W.R. et al. (March 1998). "Treatment of Intractable Pain with Topical Large-Dose Capsaicin: Preliminary Report," <i>Anesth. Analg.</i> 86(3):579-583.	
/M.Y./	26.	Roberts, M.S. et al. (1993). "Water: The Most Natural Penetration Enhancer" Chapter 1 in <i>Pharmaceutical Skin Penetration Enhancement</i> . Walter, K.A. et al. eds., Marcel Dekker: New York, NY, pp. 1-30.	
/M.Y./	27.	Rowbotham, M. et al. (December 2, 1998). "Gabapentin for the Treatment of Postherpetic Neuralgia: A Randomized Controlled Trial," <i>JAMA</i> 280(21):1837-1842.	
/M.Y./	28.	Rowbotham, M.C. et al. (April 1996). "Lidocaine Patch: Double-Blind Controlled Study of a New Treatment Method for Post-Herpetic Neuralgia," <i>Pain</i> 65(1):39-44.	
/M.Y./	29.	Simpson, D. et al. (2006). "Controlled Study of High-Concentration Capsaicin Patch for Painful HIV-Associated Distal Sensory Polyneuropathy," <i>13th Conference on Retroviruses and Opportunistic Infections</i> , located at < <a href="http://www.retroconference.org/2006/Abstracts/26135.html">http://www.retroconference.org/2006/Abstracts/26135.html</a> >, last visited on July 28, 2006, one page, Abstract No. 79.	
/M.Y./	30.	Smith, E.W. et al. (1995). "Percutaneous Penetration Enhancers: The Fundamentals" Chapter 1.1 in <i>Percutaneous Penetration Enhancers</i> . Smith, E.W. et al. eds., CRC Press: Boca Raton, FL, pp. 1-4.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
pa-1086504			